

REMARKS

Summary of the Office Action

Claims 1-4, and 7 have been rejected under 35 USC 103(a) as allegedly obvious over U.S. Patent No. 6,264,625 to Rubenstein et al. ("*Rubenstein*").

Claims 5 and 6 have been rejected 35 USC 103(a) as allegedly obvious over *Rubenstein* in view of U.S. Patent No. 5,947,911 to Wong et al. ("*Wong*").

Claims 33 and 35 have been rejected under 35 USC 103(a) as allegedly obvious over *Rubenstein* in view of U.S. Patent No. 5,575,770 to Melsky et al. ("*Melsky*").

Response to the Office Action

Claims 1-7 and 12-35 are pending in the application. Claims 12-32 and 34 have been withdrawn from examination, and claim 5, 6, and 33 have been amended herein. Therefore, upon entry of the present amendment, claims 1-7, 33 and 35 will be subject to examination.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claim 1-4 and 7 are not obvious over *Rubenstein* at least because *Rubenstein* fails to teach or suggest that "the pump is disposed in a housing made of a biocompatible material and having an anti-infective coating."

The Examiner has admitted that *Rubenstein* does not disclose the above limitation but has argued that such limitation is obvious in view of *Rubenstein*'s teaching of the need for bacteria and other infective agents in the CSF to be neutralized prior to fluid transfer.

Rubenstein teaches at col. 9, lines 47-48:

The inner wall of the portion of container 52 that forms chamber 56 may be coated with antibodies specific to particular agents present in the cerebrospinal fluid That is, the antibodies may be linked or bound to the inner wall of chamber 56 so that they may capture putative toxic chemicals and draw them out of solution, keeping the driving

concentration gradient between cerebrospinal fluid and dialysate high. Alternatively, the antibodies may be bound to beads, strands or other structures which may be periodically introduced into and retrieved from the dialysate chamber through dialysate port 60.

As the above quotation shows, *Rubenstein* teaches the removal of “putative toxic chemicals” from the cerebrospinal fluid, which are defined at col. 4, lines 59-62 as “deleterious materials in the patient's cerebrospinal fluid, such as neurotoxic substances and substances associated with histologic lesions.”

Therefore, *Rubenstein* teaches the use of antibodies to filter out certain substances from the cerebrospinal fluid and not to fight bacteria causing infections developing near the housing of the pump. Such antibodies can act on the cerebrospinal fluid by being in contact with the cerebrospinal fluid (as taught by *Rubenstein*, by being disposed on a bag or container 52), and are not disposed on the housing of the pump, as claimed in Applicant's claim 1 and in the claims depending therefrom.

The difference between the teachings of *Rubenstein* and of Applicant can be better understood by considering that *Rubenstein* teaches a purification of the cerebrospinal fluid, while Applicant teaches an anti-infective coating to prevent infections from bacterial colonies that form in tissue adjacent to the pump, as observed in fluid removal systems in the prior art.

For at least this reason, claim 1 and the claims depending therefrom are not obvious in view of the prior art of record and the withdrawal of the rejections under 35 USC 103(a) is respectfully requested.

Claims 5-6 are not obvious over *Rubenstein* in view of *Wong* also because those references, alone or in combination, do not teach or suggest the limitation “wherein the chemical composition is detected by an implanted sensor.”

Rubenstein does not teach the use of chemical sensors, as the Examiner has admitted, and *Wong* teaches the use of a blood analyzer disposed outside of the patient's body, therefore, not “implanted.”

Claim 33 is not obvious over *Rubenstein* in view of *Melsky* also because those two references, alone or in combination, do not teach or suggest the limitation “wherein the anchors are selected from the group consisting of barbed insertion pins, a screw threading defined on an outside surface of the pump, staples, adhesive compounds, one or more pins designed to be inserted into the abdominal wall, and combinations thereof.”

Rubenstein does not teach the use of anchoring means, as the Examiner has admitted, and *Melsky* teaches the use of rings extending from the pump and stitched to adjacent body tissue, therefore, not anchored as recited in claim 33.

Claim 35 is not obvious over *Rubenstein* in view of *Melsky* also because those two references, alone or in combination, do not teach or suggest the limitation “wherein the housing comprises a material promoting fibrotic ingrowth into the housing.”

Applicant was unable to find teachings in *Melsky* related to the use of biocompatible materials or materials promoting fibrotic ingrowth. Applicant found teachings in *Rubenstein* related to the use of biocompatible materials, the examples cited by *Rubenstein* being stainless steel, a relatively inert polymer such as polytetrafluoroethylene, and silicone. Applicant does not dispute that the cited references teach that such materials are biocompatible, but disputes that the cited references teach that such materials “promote” fibrotic ingrowth.

To make an example, fibrotic ingrowth may occur in stents, but not because of the biocompatible nature of the material forming the stent, but because of the cellular nature of the stent, which causes fibrotic ingrowth to occur within the cell openings. Therefore, biocompatible materials are not understood by Applicant as inherently promoting fibrotic ingrowth.

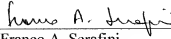
For at least the above reasons, reconsideration of the rejections of claims 1-7, 33 and 35 is respectfully requested.

Conclusion

In view of the foregoing comments, it is respectfully submitted that the application is now in condition for allowance. Reexamination and reconsideration of the pending claims are respectfully requested.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Franco A. Serafini", is written over a horizontal line.

Franco A. Serafini

Reg. No. 52,207

Attorney for Applicant

LUCE, FORWARD, HAMILTON & SCRIPPS, LLP
11988 El Camino Real, Suite 200
San Diego, California 92130
Tel: (858) 720-6320
Fax: (858) 523-4326

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